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EXAMINER

RUSSEL, JEFFREY E

ART UNIT PAPER NUMBER

1654

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,702

Applicant(s)

LUKE ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11 is/are allowed.
- 6) ☒ Claim(s) 1 and 12-17 is/are rejected.
- 7) ☒ Claim(s) 2-10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1. The Sequence Listing filed some time between January 16, 2003 and February 19, 2003 (the records available to the examiner are incomplete, and thus he can not determine exactly when the sequence listing was submitted) has been approved by STIC for matters of form. However, the paper copy of the sequence listing and the statements that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b), are missing from the file wrapper. If no changes to the sequence listing are required after consideration of the following objection, Applicants are required to submit replacement copies of the paper copy of the sequence listing and the statements.

The sequence listing amendment filed in January/February 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: There is no original disclosure in the application of SEQ ID NOS:1 and 2 as defined in the computer readable form of the sequence listing. Amino acid sequences having 393 and 243 amino acids are not recited in the original disclosure.

If changes to the sequence listing are required in response to the above objection, then Applicant is required to cancel the new matter in the reply to this Office Action by providing a substitute computer readable form (CRF) copy of the Sequence Listing, a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

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2. The abstract of the disclosure is objected to because it should not refer to any particular claim numbers. It is recommended that the phrase "in claim 1" be changed to "herein".

Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: At page 1, line 22, "it" should be changed to "its". At page 16, lines 11-12, is a sentence fragment. At page 25, line 24, "subcloned" is misspelled. At page 26, line 12, "to" (second occurrence) should be deleted. At page 26, line 18, a SEQ ID NO must be inserted after the nucleic acid sequence. See 37 CFR 1.821(d). Appropriate correction is required.

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "Use" is not a statutory class of invention.

5. Claims 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what constitutes a "use" as is recited in instant claims 13 and 14. It is not clear if Applicants are claiming, e.g., a compound with an intended use limitation, or a method of using a compound. If the latter is intended, the claims are indefinite because they are drawn to a method, but no positive process steps are recited. Claim 13 is indefinite because it is incomplete - formula (1) is not recited in the body of the claim. Claims are to be complete in and of themselves, and Applicants have not shown that there is no other practical way to define the invention, e.g., by reciting formula (I) verbatim in the claim. See MPEP 2173.05(s). For analogous reasons, claims 15 and 16 are indefinite because they are incomplete - formula (4) is

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not recited in the claims. For analogous reasons, claim 17 is indefinite because it is incomplete - the variables L_1 , n , and R_{1-5} are not defined in the claim, and the claim is not in proper dependent claim format for it to be able to rely upon definitions of the variables in previous claims.

6. Claims 1, 7, 10, 14, and 17 are objected to because of the following informalities: At claim 1, page 45, line 1, "or" should be inserted after "(2)". At claim 1, page 45, line 6, "or" should be inserted before "imidazolo". At claim 1, page 45, line 16, "or" should be inserted between "methyl" and "ethyl". At claim 1, page 45, line 20, a semicolon should be inserted at the end of the line. Claim 7 does not end with a period. Claim 10 ends with a comma rather than with a period. At claim 14, page 49, line 1, "or" should be inserted after "(5)". At claim 14, page 49, line 6, "or" should be inserted before "imidazolo". At claim 14, page 49, line 16, "or" should be inserted between "methyl" and "ethyl". At claim 14, page 49, line 20, a semicolon should be inserted at the end of the line. Claim 17 is not in single sentence format - there is an internal period followed by a capitalized word at lines 7-8. Appropriate correction is required.

7. Claim 12 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to other claims in the alternative only. See MPEP § 608.01(n).

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976); *In re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

9. Claims 13, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by the Japanese Patent Application 03-127732 (which is the equivalent of References UR and UV, cited in the International Search Report and in the Information Disclosure Statement filed March 7, 2001). The Japanese Patent Application '732 teaches compound 13 (see page 99), which is the compound excluded by the proviso inserted at Applicants' claim 1, page 46, lines 5-6, and teaches the therapeutic use of this compound. However, this proviso has not been inserted into claims 13, 14, and 16. With respect to these claims, an intended use limitation does not impart patentability to product claims which are otherwise anticipated by or obvious over the prior art.

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10. Claim 17 is rejected under 35 U.S.C. 103(a) as being obvious over the Japanese Patent Application 03-127732. Application of the Japanese Patent Application '732 is the same as in the above rejection of claims 13, 14, and 16. The Japanese Patent Application '732 does not teach forming its compound 13 by reacting the carboxylic acid of Applicants' formula (8) with the amine/piperazine of Applicants' formula (9). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to form compound 13 of the Japanese Patent Application '732 by reacting the corresponding carboxylic acid with the amine/piperazine because such a reaction is a common method of forming amide-containing compounds, and because the method of synthesis would not have been expected to affect the therapeutic activity of the resultant compound.

11. Claims 1 and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent Application 771,565 (which is the equivalent of Reference P15, cited in the Information Disclosure Statement filed March 10, 2003). The European Patent Application '565 teaches compound 1 (see page 8, Table 1), which corresponds to Applicants' compounds of formula (1) in which R_1 and R_3 are hydrogen; R_2 is halo; $n=1$; R_4 is aryl; L_1 is hydrogen; R_5 is $R_6C(O)-$; and R_6 is heterocyclyl substituted with C_2 alkoxycarbonyl. The compounds of the European Patent Application '565 are combined with pharmaceutically acceptable carriers and are used as antitumor drugs. See, e.g., page 13, line 4 - page 14, line 17; and page 38, lines 7-11.

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being obvious over the European Patent Application 771,565. Application of the European Patent Application '565 is the same as in the above rejection of claims 1 and 12-16. The European Patent Application '565 does not teach forming its compound 1 by reacting the carboxylic acid of Applicants' formula (8) with the

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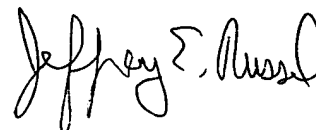
amine/piperazine of Applicants' formula (9). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to form compound 1 of the European Patent Application '565 by reacting the corresponding carboxylic acid with the amine/piperazine because such a reaction is a common method of forming amide-containing compounds (and is used in Reference Example 3, page 15, of the European Patent Application '565 to form an analogous compound), and because the method of synthesis would not have been expected to affect the therapeutic activity of the resultant compound.

13. Claim 11 is allowed. Claims 2-6, 8, and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 7 and 10 would be allowable if rewritten to overcome the claim objection set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The prior art of record does not teach or suggest compounds having the structures recited in instant claims 2-11. The claimed compounds are not generically embraced by the structural formulas disclosed in the prior art of record, and are not rendered obvious by the particular compounds of the Japanese Patent Application 03-127732 and the European Patent Application 771,565 discussed in the above rejections.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

June 17, 2003